

REMARKS

The only issue outstanding in the Office Action mailed August 21, 2007, is the new rejection of Claim 15 under 35 U.S.C. §112, first paragraph. Reconsideration of this rejection is respectfully requested.

It is argued, for example at page 3 of the Office Action, that treatment of schizophrenia and psychosis is not enabled by the present specification. The only reason apparently advanced for this determination is that the indications recited are "complex and puzzling" and there is "no absolute predictability." First, it is respectfully submitted that *absolute* predictability is unnecessary. See, for example, in *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). The Office Action does not suggest that a given material within the scope of the claims would be ineffective to treat either of the recited indications. In fact, it is clear that recitations in an Applicants' specification *must* be taken by the PTO as an assertion that all compounds encompassed in the claims are operative in the invention, in the absence of reasons or evidence to the contrary. See *Marzocchi*, *supra*.

The first paragraph of 35 U.S.C. §112 requires only *objective* enablement. Where a specification teaches the manner and process of making and using the invention, the specification *must* be taken as sufficient under §112, unless there is reason to doubt the truth of these statements. See *Marzocchi*, *supra*. Applicants' specification clearly enables one to make and use the disclosed compounds in the claimed methods.

On the one hand, it is submitted that the Examiner has not provided any such reasons or evidence to doubt the assertion of utility in the specification and, thus, the further steps of the analysis as set forth in *Marzocchi* are not reached. The alleged unpredictable nature of the cited indications which can be treated by the mechanism of action of the compounds does not rise

to the level of such reasons or evidence, as clearly stated in *Marzocchi*.

Further, in this regard, it is important to note, as a matter of law, that it is not necessary for Applicants' *method* claims to exclude inoperative embodiments, inasmuch as the claims are interpreted in light of the level of understanding one of ordinary skill in the art and, for methods, are interpreted to be *per se* functional. See *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976) and *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (CCPA 1974). These cases state that, for method claims, inoperative embodiments are not encompassed therein and the only question is whether it would be undue experimentation for one of ordinary skill in the art to determine the scope of the claim. This issue is discussed more fully below.

Thus, the only way that the issue of "undue experimentation" come up is if the PTO were to furnish reasons or evidence why the objective enablement of the present specification fails (none have been advanced) or it is alleged it would have been undue experimentation to determine the *scope* of the present method claims. This allegation has not been advanced, but instead, it is argued to be undue to determine if a given patient can be effectively treated.

Thus, the discussion of *In re Wands*, taking up a substantial amount of the Office Action, does *not* provide the necessary reasons or evidence as to why utility is deficient, but instead is reached only in other circumstances.

In any event, the claims have been amended in order to recite various indications listed in the specification at page 4, last paragraph. These indications are clearly enabled by the specification which teaches that the compounds of the invention bind specifically to 5-HT receptors and inhibit serotonin reuptake. The specification teaches that this activity, which can be measured as discussed at page 3 of the specification, enables the various utilities recited in claim 15. See page 4.

Accordingly, it is submitted that the claims are fully enabled, and withdrawal of the

rejection is respectfully requested. Should the examiner have any questions or comments, she is cordially invited to telephone the undersigned at the number set forth below.

No fee is believed to be due with this Reply, however, the Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney Docket No.: MERCK-3020

Date: November 21, 2007

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